IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. CHRISTOPHER F. MANACCI, MATTHEW H. EVENHOUSE, and NGI CLINICS LLC, Defendants.	)	Case No.: JUDGE <u>COMPLAINT</u>

PRELIMINARY STATEMENT

1. Defendants Christopher F. Manacci, Matthew H. Evenhouse, and NGI Clinics LLC have knowingly submitted false or fraudulent claims to Medicare for services that were not reimbursable under Medicare; but for which Defendants sought reimbursement. This conduct violates the False Claims Act, 31 U.S.C. § 3729. As a result of this fraud, the United States paid Medicare Part B monies to Defendants to which they were not entitled. Defendants were unjustly enriched by these payments and were paid by mistake.

JURISDICTION AND VENUE

2. The United States brings this action under the False Claims Act, 31 U.S.C. §§ 3729–3733 and at common law.

3. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1345.

4. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) because the Defendants reside and transacted business in this district.

PARTIES

5. Plaintiff is the United States of America (United States). At all times material to this civil action, the Department of Health and Human Services (HHS) was an agency and instrumentality of the Plaintiff United States, and the Centers for Medicare and Medicaid Services ("CMS") was the component agency of HHS which administered and supervised the Medicare program, 42 U.S.C. § 1395 *et seq*. CMS contracted with a private insurance carrier to receive, adjudicate, process, and pay certain Medicare claims submitted to it by Medicare beneficiaries or providers.

6. Defendant Christopher F. Manacci (Manacci) is a nurse practitioner and the principal owner and operator of NGI Clinics LLC (NGI) and treated patients at NGI's Westlake clinic. Manacci exercised full control of NGI's daily operations and formulated NGI's business and billing policies.

7. Defendant Matthew Evenhouse (Evenhouse) is a licensed medical doctor who treated patients and acted as medical director at NGI's Westlake clinic.

8. Defendant NGI Clinics LLC, an Ohio domestic limited liability company, doing business as Nightingale Centers for Regenerative Medicine, provided various pain relief services at 1991 Crocker Road, Suite 500, Westlake, Ohio. NGI closed its only office location on or about June 1, 2020.

MEDICARE PART B PROGRAM

9. In 1965, Congress enacted Title XVIII of the Social Security Act, commonly known as Medicare. 42 U.S.C. §§ 1395 *et seq*.

10. The United States, through HHS and its component agency, CMS, administers the Supplementary Medical Insurance Program for the Aged and Disabled as established in Part B,

Title XVIII, of the Social Security Act under 42 U.S.C. §§ 1395j-1395w (Medicare Part B Program). HHS has delegated the administration of the Medicare Program to CMS.

11. The Medicare Part B Program is a federally subsidized health insurance system for persons aged sixty-five and older, or who have certain qualifying disabilities or conditions. Eligible persons may enroll in the Medicare Part B Program to obtain benefits in return for payments of monthly premiums as established by HHS. The benefits covered by the Medicare Part B Program include medical treatment and services by physicians under 42 U.S.C. § 1395k(a)(2)(B).

12. At all relevant times herein, HHS, through CMS, administered the Medicare Part B Program in the state of Ohio through a private insurance contractor, CGS Administrators, LLC (CGS), a Medicare Administrative Contractor (Medicare Contractor). CGS made payments on those claims which appeared to be eligible for reimbursement under the Medicare Part B Program.

THE MEDICARE PROVIDER AGREEMENT

13. At all relevant times herein, Ohio providers claimed Medicare Part B reimbursement from the Medicare Contractor pursuant to written provider agreements.

14. Defendants NGI, Evenhouse, and Manacci signed, or caused to be executed, provider agreements with the Medicare Program that permitted the Defendants to submit claims to, and accept payment from, the Medicare Contractor. In 2017, Evenhouse and Manacci reassigned their Medicare benefits to NGI.

15. Defendants used Evenhouse's National Provider Identifier (NPI) number to bill Medicare. All claims billed under Evenhouse's NPI were paid to NGI.

16. Providers, including the Defendants, agree to be familiar with, and abide by, Medicare laws, regulations, and policies. These agreements are conditions of participation in the

Medicare program and conditions of receiving payment from it. Providers are told that the Medicare laws, regulations, and program instructions are available through the Medicare Contractor. Medicare Contractors communicate reimbursement policies to providers, including the Defendants, through the Medicare Manual, newsletters, and other communications.

17. The Medicare Contractor receives, processes, and pays or rejects claims according to Medicare rules, regulations, and procedures.

18. Participating providers agree to bill only for services: that are covered by Medicare, that the provider actually renders, that are medically necessary to diagnose and treat illness or injury, and for which the provider maintains adequate supporting documentation. Such documentation includes test results, doctor's orders, progress notes, and operative reports.

19. To obtain reimbursement from the Medicare program, providers submit a claim form, which typically is done electronically. In particular, providers submit the CMS1500 form and/or its equivalent known as the 837P form. On the CMS 1500 form or the 837P form, the provider includes certain five-digit codes, including Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that identify the diagnosis, services rendered and for which reimbursement is sought, and the unique billing identification number of the "rendering provider" and the "referring provider or other source." 45 C.F.R. § 162.1002(a)-(b); Medicare Claims Processing Manual, Chapter 23, § 20.7 *et seq*. CMS assigns reimbursement amounts to CPT and HCPCS codes.

20. When enrolling to submit claims electronically, providers certify they will submit claims that are "accurate, complete, and truthful." *See* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf (last visited July 5, 2022).

21. The Medicare Part B Electronic Data Interchange (EDI) enrollment documentation, which is signed and submitted when a provider enrolls for electronic billing with

a Medicare Contractor, also contains an acknowledgement "that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law."

22. Health care providers are prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary, or knew or should have known were false or fraudulent. 42 U.S.C. §§ 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).

23. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 64 (1984).

24. Providing accurate CPT and HCPCS codes on claims submission forms is material to, and a condition of payment for, the Medicare program.

25. Because it is not feasible for the Medicare program, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and submit truthful and accurate certifications and claims.

26. Generally, after a provider submits the CMS 1500 or 837P form to the Medicare program, the claim is paid directly to the provider. This is done in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.

27. At all times relevant herein, Defendants submitted Medicare Part B claims to Medicare Contractor CGS. CGS then processed those claims on behalf of Medicare.

28. During the relevant time period, Medicare did not cover acupuncture and did not deem it medically necessary. *See e.g.*, National Coverage Determination (NCD) 30.3. "Medicare

reimbursement for acupuncture, as an anesthetic or as an analgesic or for other therapeutic purposes, may not be made. Accordingly, acupuncture is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act." *Id.*

29. "P-stim", short for Point-Stimulation Therapy, is a miniaturized electro-acupuncture device worn by the patient that administers pulses of a low-level electrical current via the ear over several days.

30. Electro-acupuncture devices, including but not limited to P-Stim devices, are applied behind the ear using an adhesive and/or with needles inserted into the patient's ear.

31. The Stivax neurostimulator is a brand of P-Stim device advertised by its manufacturer as a single use, battery-powered, electrical nerve stimulator which is used for the stimulation of the vagus nerve via the ear to treat pain and various neuropathies.

32. The 501(k) Indications for Use issued by the U.S. Food and Drug Administration for the Stivax neurostimulator further describes the device as follows:

> Device Description:
> The Stivax is a single use, battery-powered, electrical nerve stimulator which is used for the stimulation of the vagus nerve via the ear. The device connects an electrode cable to two sterile (radiation) acupuncture needles that have been applied by a healthcare practitioner. The stimulator connects to a clip holder on medical grade adhesive tape. The stimulator (with tape) adheres to the patient, behind the ear.

33. The Stivax neurostimulator is never implanted and no surgery is performed. Instead of surgically implanting wires, electrical impulses are delivered to the nervous system via two tiny needles that are connected to the patient's ear using tape. The device's only legitimate use is for acupuncture; which was not covered by Medicare during the relevant time period.

FACTS

34. From on or about August 18, 2017 through on or about October 10, 2018, Defendants treated Medicare patients experiencing pain symptoms with the Stivax neurostimulator at NGI's Westlake clinic.

35. NGI billed Medicare for the Stivax neurostimulator device using Evenhouse's NPI number. In 2017, Evenhouse assigned his Medicare benefits to NGI and all payments went to NGI.

36. The primary code that Defendants used to bill Medicare for the Stivax neurostimulator was HCPCS Code L8679.

37. HCPCS Code L8679 is defined as an "[i]mplantable neurostimulator, pulse generator, any type."

38. Implantable neurostimulators (HCPCS Code L8679) are Medicare-covered devices that require surgical implantation into the central nervous system or targeted peripheral nerve and are usually implanted via procedures performed in operating rooms. *See* CMS Publication 100-03, NCD Manual, Section 160.7.

39. 21 C.F.R. § 882.5870(a), entitled "Implanted peripheral nerve stimulator for pain relief", states that:

> Identification. An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

40. 21 C.F.R. § 801.3 states that:

> Implantable device means a device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device is regarded as an implantable device

> for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health.

41. Medicare regulations and guidance are clear that an "implantable" device "requires surgery." *See* CMS Publication 100-03, NCD Manual, Section 160.7.

42. While both the P-Stim devices and implantable neurostimulators can be used to treat chronic pain, the P-Stim devices are non-invasive (i.e., do not require surgical implantation and/or an incision) and have an external battery source.

43. The Stivax neurostimulator billed by Defendants was never implanted and no surgery was performed. Instead, electrical impulses were delivered to the nervous system via two tiny needles that were connected to the patient's ear using tape. The device's only legitimate use is for acupuncture; which was not then covered by Medicare.

44. According to the 501(k) issued by the U.S. Food and Drug Administration, "Stivax is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states."

45. The NCD for Acupuncture (30.3), in effect during the relevant time period, stated "acupuncture is not considered reasonable and necessary" within the meaning of Section 1862(a)(1) of the Social Security Act. This was a long-standing determination and was widely known throughout the relevant time period. Thus, Defendants knew or should have known that acupuncture, in any form, was not reimbursable by Medicare.

46. To circumvent the prohibition against coverage for acupuncture and get paid by Medicare, Defendants improperly coded the Stivax P-Stim device as an implantable neurostimulator, HCPCS Code L8679.

47. From on or about September 13, 2017 through on or about October 17, 2018, Defendants submitted to Medicare Part B approximately 181 claims for payment using HCPCS Code L8679 and were paid approximately $1,086,707.79.

48. In conjunction with billing for treatment using the Stivax neurostimulator, Defendants also improperly billed Medicare for several CPT Codes that cover services for implanting a neurostimulator pulse generator. Since the Stivax P-Stim device is not an implantable neurostimulator, and no surgery was performed to adhere it to the patients, Defendants improperly billed: CPT Code 64553 "implantation of cranial nerve neurostimulator electrodes, accessed through the skin;" CPT Code 64585 "revision or removal of peripheral neurostimulator electrode array;" and CPT Code 63663 "revision and replacement of spinal neurostimulator electrodes." Medicare does not cover services that are "related to" non-covered services. *See* Medicare Benefit Policy Manual, Ch. 16 § 180.

49. From on or about September 13, 2017 through on or about October 17, 2018, Defendants submitted to Medicare Part B approximately 179 claims for payment using CPT Code 64553 and were paid approximately $76,178.74.

50. From on or about September 13, 2017 through on or about October 17, 2018, Defendants submitted to Medicare Part B approximately 12 claims for payment using CPT Code 64585 and were paid approximately $1,357.83.

51. From on or about September 13, 2017 through on or about October 17, 2018, Defendants submitted to Medicare Part B approximately two claims for payment using CPT Code 63663 and were paid approximately $1,192.60.

52. In total, from on or about September 13, 2017 through on or about October 17, 2018, Defendants submitted to Medicare Part B approximately 374 claims for payment using HCPCS Code L8679 and CPT Codes 64553, 64585, and 63663; the Medicare program paid

Defendants approximately $1,165,436.96 for treatments provided to Medicare beneficiaries in connection with the Stivax neurostimulator device.

53. All of Defendants' claims for HCPCS Code L8679 in conjunction with CPT Codes 64553, 64585, and/or 63663 that were submitted for reimbursement to Medicare were false and not reimbursable by Medicare.

54. Defendants' false claims were material to Medicare's decision to reimburse the claims. Medicare would not have paid for these claims if it knew Defendants were not actually providing the services for which they were billing. Publicly available guidance requires that implantable devices require surgery. CMS Publication 100-03, NCD Manual, Section 160.7. Defendants were not performing surgery but were using codes to indicate that they were. The government routinely denies payment, or seeks to recoup payments already made, for claims where the services billed were not actually performed. *See e.g.*, *Physician Agrees to Pay $375,000 to Resolve False Claims Act Allegations of P-Stim Device Fraud* (Dec. 13, 2021), https://www.justice.gov/usao-sdms/pr/physician-agrees-pay-375000-resolve-false-claims-act-allegations-p-stim-device-fraud; *U.S. Attorney Announces Four Additional Enforcement Actions as Part of Data-Driven National Effort to Combat P-Stim Fraud Scheme and Recover Millions* (Oct. 14, 2021), https://www.justice.gov/usao-edpa/pr/us-attorney-announces-four-additional-enforcement-actions-part-data-driven-national.

55. By way of example, Defendants submitted to, and were paid by, the Medicare Contractor, for the following claims in connection with the Stivax neurostimulator device. For the reasons outlined above, these claims were excluded from coverage and not reimbursable by Medicare Part B.

Claim Number	Date of Service	Codes	Amount Paid	Date of Payment
231018204253720	7-18-2018	64553	$852.43	7-27-2018
		L8679	$6,532.77	
230918236305110	8-21-2018	64553	$852.43	8-24-2018
		L8679	$6,532.77	

56. Defendants knew or should have known that the aforementioned treatments performed during the relevant time period were excluded from coverage under Medicare Part B.

COUNT I
Violation of the False Claims Act
31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A)

57. Plaintiff incorporates by reference paragraphs 1 through 56 of this Complaint as if fully rewritten herein.

58. By the acts described above, Defendants knowingly presented, or caused to be presented to an officer or employee of the United States Government, false or fraudulent claims through the Medicare Part B Program, for payment or approval in violation of 31 U.S.C. § 3729(a)(1) and 31 U.S.C. § 3729(a)(1)(A).

59. The United States paid the false or fraudulent claims because of Defendants' acts, and incurred damages as a result.

60. Pursuant to 31 U.S.C. § 3729(a)(1), Defendants are liable to the United States for three times the amount of all damages sustained by the United States because of Defendants' conduct.

61. Pursuant to 31 U.S.C. § 3729(a)(1) and 28 C.F.R. § 85.5(a)(9), Defendants are liable to the United States for a civil penalty of not less than $12,537 and not more than $25,076 for each violation of the False Claims Act.

COUNT II
UNJUST ENRICHMENT

62. Plaintiff incorporates by reference paragraphs 1 through 61 of this Complaint as if fully rewritten herein.

63. This is a claim for the recovery of monies by which Defendants have been unjustly enriched.

64. By directly or indirectly obtaining government funds to which they were not entitled, Defendants were unjustly enriched, and are liable to account for and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

COUNT III
PAYMENT BY MISTAKE

65. Plaintiff incorporates by reference paragraphs 1 through 64 of this Complaint as if fully rewritten herein.

66. The United States has paid money to Defendants for services provided under the Medicare Program.

67. The United States paid Defendants that money based upon a mistaken belief that the services provided were covered under the Medicare Program. The United States would not have paid for such claims had it known the true facts.

68. The United States would not have paid Defendants if the United States had not been mistaken, resulting in damages to the United States in an amount to be determined at trial.

WHEREFORE**,** Plaintiff demands that judgment be entered in its favor and against Defendants as follows:

A. On COUNT ONE in the amount of triple Plaintiff's damages plus penalties as allowed by law;

B. On COUNT TWO in the amount of Plaintiff's damages plus prejudgment interest;

C. On COUNT THREE in the amount of Plaintiff's damages plus prejudgment interest;

D. On ALL COUNTS for the costs of this action, and such other and further relief to which Plaintiff may be entitled.

Respectfully submitted,

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